

# **EXHIBIT 50**

## CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

<div>Page 1</div> <div>UNITED STATES DISTRICT COURT DISTRICT of MINNESOTA  ----- In Re: Bair Hugger Forced Air Warming Products Liability Litigation  This Document Relates To: All Actions            MDL No. 15-2666 (JNE/FLM) -----  DEPOSITION of THEODORE R. HOLFORD VOLUME I, PAGES 1 - 386 JULY 18, 2017  (The following is the deposition of THEODORE R. HOLFORD, taken pursuant to Notice of Taking Deposition, via videotape, at the Marriott Hartford Downtown, 200 Columbus Boulevard, Hartford, Connecticut, commencing at approximately 9:20 o'clock a.m., July 18, 2017.)</div>	<div>Page 3</div> <div>INDEX <table><thead><tr><th>EXHIBITS</th><th>DESCRIPTION</th><th>PAGE MARKED</th></tr></thead><tbody><tr><td>Ex 1</td><td>Expert Report of Theodore R. Holford, PhD</td><td>11</td></tr><tr><td>2</td><td>Holford curriculum vitae</td><td>11</td></tr><tr><td>3</td><td>Expert report of Jonathan M. Samet</td><td>11</td></tr><tr><td>4</td><td>Albrecht October 7, 2016 deposition excerpts</td><td>23</td></tr><tr><td>5</td><td>Augustine Biomedical + Design Research and Development Report, 9/14/2007</td><td>24</td></tr><tr><td>6</td><td>Article, Forced-Air Warming Design: Evaluation of Intake Filtration, Internal Microbial Buildup, and Airborne-Contamination Emissions, by Reed, et al</td><td>28</td></tr><tr><td>7</td><td>Article, Predicting bacterial populations based on airborne particulates: A study performed in nonlaminar flow operating rooms during joint arthroplasty surgery, by Stocks, et al</td><td>46</td></tr><tr><td>8</td><td>E-mail string, 3MBH00050770-1</td><td>50</td></tr></tbody></table></div>	EXHIBITS	DESCRIPTION	PAGE MARKED	Ex 1	Expert Report of Theodore R. Holford, PhD	11	2	Holford curriculum vitae	11	3	Expert report of Jonathan M. Samet	11	4	Albrecht October 7, 2016 deposition excerpts	23	5	Augustine Biomedical + Design Research and Development Report, 9/14/2007	24	6	Article, Forced-Air Warming Design: Evaluation of Intake Filtration, Internal Microbial Buildup, and Airborne-Contamination Emissions, by Reed, et al	28	7	Article, Predicting bacterial populations based on airborne particulates: A study performed in nonlaminar flow operating rooms during joint arthroplasty surgery, by Stocks, et al	46	8	E-mail string, 3MBH00050770-1	50
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<div>Page 2</div> <div>1 APPEARANCES: 2 On Behalf of the Plaintiffs: 3 Michael A. Sachet and Jan M. Conlin 4 CIRESI CONLIN L.L.P. 5 225 South 6th Street, Suite 4600 6 Minneapolis, Minnesota 55402 7 8 On Behalf of Defendants: 9 Corey L. Gordon 10 BLACKWELL BURKE P.A. 11 432 South Seventh Street, Suite 2500 12 Minneapolis, Minnesota 55415 13 ALSO APPEARING: 14 Ronald M. Huber, Videotechnician 15 16 17 18 19 20 21 22 23 24 25</div>	<div>Page 4</div> <div>1 9 Article, Association of Airborne 2 Microorganisms in the Operating 3 Room With Implant Infections: A 4 Randomized Controlled Trial, by 5 Darouiche, et al 54 6 10 Proceedings of the International 7 Consensus Meeting on Peri- 8 prosthetic Joint Infection 67 9 11 Van Duren March 7, 2017 10 transcript excerpt 77 11 12 Article, Convection warmers -- 12 a possible source of contamination 13 in laminar airflow operating 14 theatres? by Tumia, et al 80 15 13 Article, Forced-air warming 16 and ultra-clean ventilation do 17 not mix, by McGovern, et al 94 18 14 Computer printout, AUGUSTINE_ 19 0005193-487 104 20 15 Albrecht October 7, 2016 21 deposition excerpt 123 22 16 LogisticRegression analysis, 23 Albrecht, March 11, 2016, 24 Albrecht_0002275-8 135 25 17 Gmail string 140</div>																											

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<p style="text-align: right;">Page 93</p> <p>1 on the tabulation of the data; correct?</p> <p>2 MR. GORDON: Object to the form of the</p> <p>3 question.</p> <p>4 <b>A. I -- I suppose he might have. I mean the</b></p> <p>5 <b>other -- the other authors certainly did.</b></p> <p>6 Q. And that's why you reviewed their deposition</p> <p>7 testimony; correct?</p> <p>8 <b>A. That's -- that's part of what I -- what I --</b></p> <p>9 <b>what came out of my review of their testimony, yes.</b></p> <p>10 Q. Is --</p> <p>11 So everything that's been marked on page 14</p> <p>12 of your report, in addition to the recent Augustine</p> <p>13 study, are the materials that you reviewed in drafting</p> <p>14 your report and providing testimony today.</p> <p>15 <b>A. Well the recent Augus -- Augustine study I</b></p> <p>16 <b>saw after --</b></p> <p>17 Q. Yes.</p> <p>18 <b>A. -- this was submitted, so that's not on here</b></p> <p>19 <b>because I -- I hadn't seen it when I wrote this.</b></p> <p>20 Q. But that's the totality of evidence up to</p> <p>21 this point in time.</p> <p>22 <b>A. That's pretty much it, yes. Yes.</b></p> <p>23 MR. GORDON: I -- I think he also reviewed</p> <p>24 the Samet testimony about the Augustine article.</p> <p>25 THE WITNESS: Oh, I'm sorry, yes.</p>	<p style="text-align: right;">Page 95</p> <p>1 Exhibit 13. The title is "Forced-air warming and</p> <p>2 ultra-clean ventilation do not mix" by McGovern et al;</p> <p>3 correct?</p> <p>4 <b>A. Correct.</b></p> <p>5 Q. I do not know whether you will need the</p> <p>6 study to answer these questions, but feel free to</p> <p>7 refer to it as you see fit.</p> <p>8 There were two components to this study;</p> <p>9 correct?</p> <p>10 <b>A. That's correct.</b></p> <p>11 Q. There was a study of bubbles in an</p> <p>12 experimental setting, and then there was the</p> <p>13 observational data aspect of the study; correct?</p> <p>14 <b>A. Yes.</b></p> <p>15 Q. And the first part of the study, which we've</p> <p>16 discussed a little bit, found a significant increase</p> <p>17 in the amount of bubbles over the surgical site in</p> <p>18 this experimental study when the Bair Hugger was used</p> <p>19 compared to a conductive warming device; correct?</p> <p>20 <b>A. That's what they report, yes.</b></p> <p>21 Q. Okay. And the second part, which involved</p> <p>22 the observational data set, involved 1,437 patients;</p> <p>23 correct?</p> <p>24 <b>A. I think that's right.</b></p> <p>25 Q. Table II, you might have to do a little</p>
<p style="text-align: right;">Page 94</p> <p>1 MR. SACCHET: Okay.</p> <p>2 THE WITNESS: There was also that.</p> <p>3 Q. Okay. So no other articles other than</p> <p>4 what's been listed on page 14.</p> <p>5 <b>A. No.</b></p> <p>6 Q. And no other deposition transcripts aside</p> <p>7 from Samet and I think you said Augustine.</p> <p>8 <b>A. I saw -- I saw just a couple of pages of --</b></p> <p>9 <b>of Augustine, but --</b></p> <p>10 Q. Okay. Did you perform any independent</p> <p>11 investigation outside of what was provided to you?</p> <p>12 <b>A. No.</b></p> <p>13 Q. So everything that you're relying on is what</p> <p>14 3M provided to you.</p> <p>15 <b>A. That's correct.</b></p> <p>16 Q. Okay. With respect to the McGovern study,</p> <p>17 I'd like to review that quickly. I assume that we are</p> <p>18 on the same page, doctor, with calling this study "the</p> <p>19 McGovern study," which is the one that you discuss in</p> <p>20 your report; correct?</p> <p>21 <b>A. Yes.</b></p> <p>22 <b>(Exhibit 13 was marked for</b></p> <p>23 <b>identification.)</b></p> <p>24 BY MR. SACCHET:</p> <p>25 Q. We have handed you what has been marked as</p>	<p style="text-align: right;">Page 96</p> <p>1 math, --</p> <p>2 <b>A. Yeah.</b></p> <p>3 Q. -- or I believe on page 1541 you'll see it</p> <p>4 in the bottom left-hand corner.</p> <p>5 <b>A. Yeah. Okay.</b></p> <p>6 <b>Yeah, 1066 and 371 are the two groups.</b></p> <p>7 Q. Which adds up though 1437.</p> <p>8 <b>A. Okay. Yeah, right.</b></p> <p>9 Q. And the -- the study period was 2.5 years;</p> <p>10 correct?</p> <p>11 <b>A. I think that's right, yes.</b></p> <p>12 Q. You can look at page 1540 --</p> <p>13 <b>A. Yeah.</b></p> <p>14 Q. -- on the left-hand side under "Joint</p> <p>15 Infection data."</p> <p>16 <b>A. Right.</b></p> <p>17 Q. And deep joint infections as opposed to</p> <p>18 superficial or wound infections was the outcome of</p> <p>19 interest; correct?</p> <p>20 <b>A. That's correct.</b></p> <p>21 Q. And there were three warming phases, there</p> <p>22 was the Bair Hugger period, a transitional period, and</p> <p>23 a conductive warming period; correct?</p> <p>24 <b>A. That's correct.</b></p> <p>25 Q. And during the Bair Hugger period there was</p>

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<p>1 a change in the antibiotic; correct?</p> <p>2 <b>A. That's correct.</b></p> <p>3 Q. The first antibiotic was Gentamicin;</p> <p>4 correct?</p> <p>5 <b>A. Yes.</b></p> <p>6 Q. And the second antibiotic was Gentamicin</p> <p>7 plus Teicoplanin.</p> <p>8 <b>A. That's correct.</b></p> <p>9 Q. Are you comfortable referring to that</p> <p>10 protocol as GenTeic?</p> <p>11 <b>A. Okay.</b></p> <p>12 Q. There was also a change in the</p> <p>13 thromboprophylaxis.</p> <p>14 <b>A. That's right.</b></p> <p>15 Q. The first thromboprophylaxis was tinzaparin</p> <p>16 during the Bair Hugger arm of the study; correct?</p> <p>17 <b>A. Yes.</b></p> <p>18 Q. And in the last six months of the Bair</p> <p>19 Hugger arm there was a change to rivaroxaban; correct?</p> <p>20 <b>A. That's correct.</b></p> <p>21 Q. Are you okay with referring to rivaroxaban</p> <p>22 as Xarelto?</p> <p>23 <b>A. Okay.</b></p> <p>24 Q. It's just the pharmaceutical name of -- of</p> <p>25 that thrombo.</p>	<p>1 MR. GORDON: Object to the form of the</p> <p>2 question.</p> <p>3 <b>A. I don't under -- what do you mean by --</b></p> <p>4 <b>What is "marked?"</b></p> <p>5 Q. Have you asked Dr. Borak?</p> <p>6 <b>A. The meaning of --</b></p> <p>7 <b>It's -- it's not a quantitative term that</b></p> <p>8 <b>I'm familiar with.</b></p> <p>9 Q. So to the extent that Dr. Borak used that</p> <p>10 language in his report, you wouldn't feel comfortable</p> <p>11 with the same language.</p> <p>12 <b>A. I'm not fam --</b></p> <p>13 <b>I have not read his report. I mean it's</b></p> <p>14 <b>a -- it's a -- it's a -- it's a substantial -- it's a</b></p> <p>15 <b>big decline, yes.</b></p> <p>16 Q. A big decline.</p> <p>17 <b>A. It is a big difference.</b></p> <p>18 Q. And the p-value reported in Table II is</p> <p>19 .024; correct?</p> <p>20 <b>A. That's -- that is the reported value, yes.</b></p> <p>21 Q. And that reported p-value is statistically</p> <p>22 significant based on the 95 percent confidential</p> <p>23 interval; correct?</p> <p>24 <b>A. I would disagree with your language.</b></p> <p>25 Q. Okay. It's maybe not meaningful. I</p>
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<p>1 And in the Hot Dog period patients went back</p> <p>2 and received tinzaparin as opposed to Xarelto;</p> <p>3 correct?</p> <p>4 <b>A. That's correct.</b></p> <p>5 Q. Okay. So results reported in Table II of</p> <p>6 this study show that three out of 371 patients</p> <p>7 developed a deep joint infection in 60 days; correct?</p> <p>8 <b>A. That's correct.</b></p> <p>9 Q. And the percentage of that infection rate is</p> <p>10 .8 percent; correct?</p> <p>11 <b>A. Correct.</b></p> <p>12 Q. As also reported in Table II, 32 out of</p> <p>13 1,066 patients developed a deep joint infection after</p> <p>14 receiving the Bair Hugger warming; correct?</p> <p>15 <b>A. That's correct.</b></p> <p>16 Q. The change from the infection rate of the</p> <p>17 Bair Hugger --</p> <p>18 Which is three percent; correct?</p> <p>19 <b>A. Yes.</b></p> <p>20 Q. -- to the .8 percent is a marked decline; is</p> <p>21 it not?</p> <p>22 MR. GORDON: Object to the form of the</p> <p>23 question.</p> <p>24 <b>A. It -- it is -- it is lower, yes.</b></p> <p>25 Q. Would you agree that it's a marked decline?</p>	<p>1 apologize.</p> <p>2 <b>A. Yeah. It -- it -- it is significant at the</b></p> <p>3 <b>five percent level, yes.</b></p> <p>4 Q. Okay. So I always say this wrong, but</p> <p>5 perhaps you can edify me. If you have a statistically</p> <p>6 significant p-value using a 95 percent or five -- five</p> <p>7 percent threshold, --</p> <p>8 <b>A. Yes.</b></p> <p>9 Q. -- does that mean that if you repeated the</p> <p>10 study a hundred times using the same -- a similar</p> <p>11 population of patients, that you would expect the same</p> <p>12 outcome at least 95 -- 95 times out of a hundred?</p> <p>13 <b>A. No.</b></p> <p>14 Q. Okay. What --</p> <p>15 So please edify.</p> <p>16 <b>A. What that means is if -- if there is no</b></p> <p>17 <b>association and you repeat the study, you're comparing</b></p> <p>18 <b>two groups where there is no effect, then just five</b></p> <p>19 <b>percent of the time you will reject the -- you will</b></p> <p>20 <b>reject the -- the null hypothesis, which is that there</b></p> <p>21 <b>is no effect.</b></p> <p>22 Q. Okay. So is another way to think about it</p> <p>23 is there's a five-percent chance of getting a false</p> <p>24 positive?</p> <p>25 <b>A. No, it's not looking at the false positive.</b></p>

25 (Pages 97 to 100)

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<p>1 remember exactly where -- where it is.</p> <p>2 Reed said it.</p> <p>3 Q. This is Mr. Albrecht. Do you think Mr.</p> <p>4 Albrecht said there was an error?</p> <p>5 A. I seem to recall he -- that -- that there</p> <p>6 was. I don't remember exactly where -- where it is.</p> <p>7 It's a fairly long report.</p> <p>8 Q. Let's keep going then. If you can go to</p> <p>9 internal page 142, page 37 at the bottom, line 16, Mr.</p> <p>10 Gordon asked, "I have something that's going to help.</p> <p>11 But first I want to establish that -- that is a</p> <p>12 printout of the data that Dr. Reed would have provided</p> <p>13 to you and from which you generated your statistical</p> <p>14 analysis that became the observational component of</p> <p>15 Exhibit 8."</p> <p>16 Do you see that question?</p> <p>17 A. Yes.</p> <p>18 Q. I'll represent to you that Exhibit 8 is the</p> <p>19 McGovern study --</p> <p>20 A. Okay.</p> <p>21 Q. -- and I'll also represent to you that the</p> <p>22 data set that Mr. Gordon is referring to is Albrecht</p> <p>23 Exhibit 10.</p> <p>24 A. Okay.</p> <p>25 Q. The answer is, "I'm assuming, but there's no</p>	<p>1 Q. Yeah.</p> <p>2 A. Yeah.</p> <p>3 Q. And Mr. Albrecht in this testimony is saying</p> <p>4 he doesn't know whether it's the final data set.</p> <p>5 A. Okay.</p> <p>6 Q. And Mr. Albrecht also said in the testimony</p> <p>7 we read a moment ago that there were three infections</p> <p>8 in the Hot Dog arm that were analyzed with respect to</p> <p>9 the paper; correct?</p> <p>10 A. That's --</p> <p>11 He's, I assume, re -- reporting back what --</p> <p>12 what was actually published in the paper, what this</p> <p>13 tabulation that's in the paper showed.</p> <p>14 Q. He says the data set that was analyzed there</p> <p>15 was three.</p> <p>16 A. So what is he referring --</p> <p>17 When he says "data set," what does he mean?</p> <p>18 I don't know quite what he -- what he's referring to.</p> <p>19 Is he referring to the data -- the tabulation that was</p> <p>20 made from the data, or is he talking about the -- the</p> <p>21 original file?</p> <p>22 Q. You're aware that not even Mr. Gordon knows</p> <p>23 whether Exhibit 10 is the final data set; correct?</p> <p>24 MR. GORDON: Object to the form of the</p> <p>25 question, lack of foundation.</p>
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<p>1 way for me to verify something like this."</p> <p>2 A. Okay.</p> <p>3 Q. So Mr. Albrecht didn't know whether or not</p> <p>4 Albrecht Exhibit 10 was the final data set, correct,</p> <p>5 based on this testimony?</p> <p>6 A. I -- I --</p> <p>7 Yeah. Apparently, yeah.</p> <p>8 Q. But you have concluded that, based on Mr.</p> <p>9 Albrecht's testimony, that Albrecht Exhibit 10 is the</p> <p>10 final data set; is that correct?</p> <p>11 MR. GORDON: Object to the form of the</p> <p>12 question, misstates his test -- misstates prior</p> <p>13 testimony.</p> <p>14 Q. Is your testimony not that Albrecht Exhibit</p> <p>15 10 is the final data set?</p> <p>16 MR. GORDON: Same objection.</p> <p>17 A. I don't -- I don't --</p> <p>18 I'm taking Exhibit 10 as it -- as it -- as</p> <p>19 it is. I mean what --</p> <p>20 What do you mean by "final data set?"</p> <p>21 Q. Well you've already said that the data set</p> <p>22 that is in Albrecht 10 is not the data that was in the</p> <p>23 study; correct?</p> <p>24 A. A tabulation based on -- based on that --</p> <p>25 that data set doesn't agree with the paper.</p>	<p>1 A. I don't know what Mr. Gordon knows or</p> <p>2 doesn't know about that.</p> <p>3 Q. Let's look at page 163, which is 42 at the</p> <p>4 bottom. Are you there, doctor?</p> <p>5 A. Okay.</p> <p>6 Q. Line 17, Mr. Gordon asks -- or states, "And</p> <p>7 I want to make it very clear, I have no idea if</p> <p>8 Exhibit 10 is the original data" --</p> <p>9 Albrecht answers: "I don't either."</p> <p>10 Do you see that?</p> <p>11 A. Okay.</p> <p>12 Q. So Mr. Gordon doesn't know if it's the final</p> <p>13 data set, Mr. Albrecht doesn't know whether it's the</p> <p>14 final data set, Mr. Borak in his report uses the word</p> <p>15 "apparent" data set, you don't know whether it's the</p> <p>16 final data set --</p> <p>17 A. Well the question is not "final," question</p> <p>18 is "original."</p> <p>19 Q. Okay. So let's say the original data set.</p> <p>20 A. Okay.</p> <p>21 Q. Mr. Gordon doesn't know if Exhibit 10 is the</p> <p>22 original data set.</p> <p>23 A. Okay.</p> <p>24 Q. Mr. Albrecht also doesn't know whether</p> <p>25 Exhibit 10 is the original data set.</p>

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<p>1       <b>A. Yeah.</b></p> <p>2       Q. Mr. Borak also doesn't know whether Exhibit</p> <p>3       10 is the original data set.</p> <p>4       <b>A. Okay.</b></p> <p>5       Q. And you don't know.</p> <p>6       <b>A. I don't.</b></p> <p>7       Q. To the extent that you rely on Albrecht</p> <p>8       Exhibit 10, not knowing whether or not it's the</p> <p>9       original data set, it could be a data artifact issue;</p> <p>10      could it not?</p> <p>11      MR. GORDON: Object to the form of the</p> <p>12      question.</p> <p>13      <b>A. If -- if there's an error in -- in --</b></p> <p>14      <b>I mean if -- if the file is not the correct</b></p> <p>15      <b>data, then there -- there could be -- there -- there</b></p> <p>16      <b>would be a problem with -- with the analysis.</b></p> <p>17      Q. And -- and you don't know whether or not</p> <p>18      there is a problem with the data.</p> <p>19      <b>A. I don't know. I don't know if there is or</b></p> <p>20      <b>if there is not.</b></p> <p>21      Q. You know that there's a missing page.</p> <p>22      <b>A. You --</b></p> <p>23      <b>There is one missing page.</b></p> <p>24      Q. You know that the missing page contains or</p> <p>25      may not contain information regarding deep joint</p>	<p>1       Mr. Albrecht has said that the data set that was</p> <p>2       analyzed, there was three deep joint infections.</p> <p>3       <b>A. Yes.</b></p> <p>4       Q. You're making that assumption even though</p> <p>5       Mr. Gordon said that Exhibit 10, he didn't know</p> <p>6       whether it was the original data set.</p> <p>7       MR. GORDON: You're -- you're actually --</p> <p>8       You're reading only a portion of the</p> <p>9       testimony and you're --</p> <p>10      MR. SACCHET: I think you're testifying</p> <p>11      right now, Mr. Gordon.</p> <p>12      MR. GORDON: Well no. I mean --</p> <p>13      But come on.</p> <p>14      MR. SACCHET: I'm --</p> <p>15      MR. GORDON: If you're going to quote me,</p> <p>16      quote what I said; don't make -- don't -- don't --</p> <p>17      MR. SACCHET: Okay.</p> <p>18      MR. GORDON: -- don't screw up the record by</p> <p>19      selectively quoting half of what I said.</p> <p>20      MR. SACCHET: Yeah. I'll read the sentence.</p> <p>21      MR. GORDON: Read the whole sentence.</p> <p>22      MR. SACCHET: "And I want -- I want to make</p> <p>23      it very clear, I have no idea if Exhibit 10 is the</p> <p>24      original data" --</p> <p>25      MR. GORDON: And you see the thing it says</p>
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<p>1       infection during the Bair Hugger study period;</p> <p>2       correct?</p> <p>3       <b>A. It was --</b></p> <p>4       <b>I wasn't looking at the individual pages, as</b></p> <p>5       <b>I've -- as I've said, --</b></p> <p>6       Q. Yeah.</p> <p>7       <b>A. -- and -- and my under -- I --</b></p> <p>8       <b>I don't know if this is the same data set</b></p> <p>9       <b>that -- that Albrecht was -- was looking at when he</b></p> <p>10      <b>did the -- his -- his calculations.</b></p> <p>11      Q. Thank you.</p> <p>12      Do you have any other reason to assume that</p> <p>13      Albrecht Exhibit 10 is the original or final data set?</p> <p>14      MR. GORDON: Object to the form of the</p> <p>15      question.</p> <p>16      <b>A. I mean why is Exhibit 10 as part of the</b></p> <p>17      <b>Albrecht testimony?</b></p> <p>18      Q. Why is it?</p> <p>19      <b>A. Yeah. How did it get there?</b></p> <p>20      Q. Mr. Gordon marked --</p> <p>21      <b>A. Okay.</b></p> <p>22      Q. -- Exhibit 10 at the deposition.</p> <p>23      <b>A. And I mean the assumption is is that that is</b></p> <p>24      <b>the data on which this is based.</b></p> <p>25      Q. You're making that assumption even though</p>	<p>1       after that? It says dash --</p> <p>2       MR. SACCHET: Dash.</p> <p>3       MR. GORDON: -- and continues on with the</p> <p>4       rest of what I said.</p> <p>5       MR. SACCHET: -- "or the -- the newer data</p> <p>6       that's slightly conflicted."</p> <p>7       Q. Does that change your mind?</p> <p>8       <b>A. What is the question?</b></p> <p>9       Q. The question is: Mr. Albrecht has said that</p> <p>10      there was three infections in the Hot Dog period based</p> <p>11      on the data that was analyzed.</p> <p>12      <b>A. Yes.</b></p> <p>13      Q. Mr. Gordon has said he doesn't know if</p> <p>14      Exhibit 10 is the original data or the newer data</p> <p>15      that's slightly conflicted.</p> <p>16      <b>A. Yes.</b></p> <p>17      Q. Dr. Borak has said that it apparently could</p> <p>18      be.</p> <p>19      <b>A. Yes.</b></p> <p>20      Q. You just told me that you're assuming</p> <p>21      Albrecht Exhibit 10 is the final data set.</p> <p>22      MR. GORDON: I object to the form of the</p> <p>23      question.</p> <p>24      <b>A. Well I'm -- I'm -- that --</b></p> <p>25      <b>Exhibit 10 is the data on which I did the</b></p>

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<p>1 the -- with the confidence interval is it kind of  2 depends on the logarithm, so it's more on the log  3 scale, so that's part of what happens. I mean this  4 odds ratio is 4.77, so it's quite a bit bigger than  5 the odds ratios we were finding associated with Bair  6 Hugger use. So that's -- that's of course just a  7 point estimate, and so we're talking about a higher  8 range, so the range is going to be -- going to tend to  9 be somewhat wider because -- because we're up there.  10 And of course the -- the total sample size, total  11 number of individuals involved is -- is quite a bit  12 smaller than -- than -- because it -- it's just  13 based --  14 It comes out to be a subset of the -- of the  15 Bair Hugger study because it's only the Bair Hugger  16 period, so it's reduced in that way, and then the  17 other thing is that it's not the entire period, it's  18 just part of it, so we -- you're splitting that data  19 set up. And so your total sample size has gone down,  20 and that increases the -- that decreases the sample  21 size and in general makes the estimates less precise.  22 Q. But there's no doubt that the confidence  23 interval in this Jensen reanalysis, which is in your  24 report on page five, is double the width of the  25 McGovern confidence interval; correct?</p>	<p>1 A. Well the accuracy depends on -- on the -- on  2 the --  3 Q. Cross product.  4 A. Well the point estimate is the cross  5 product. The -- the confidence interval depends on  6 this Fisher-like distribution. It's not --  7 It's an exact kind of calculation that --  8 that -- that's involved, but it's kind of a lengthy  9 calculation that roughly depends on the standard  10 error.  11 Q. So I might need to back up because I don't  12 know if I'm fully understanding what you're saying.  13 But the odds ratio reported in the McGovern study was  14 3.8; correct?  15 A. Yes.  16 Q. And then in your report on page two you say  17 the odds ratio for this comparison is 2.76, and  18 what --  19 A. That's in the tabulation I used, yes.  20 Q. -- what data are you using to derive that  21 odds ratio?  22 A. The --  23 MR. GORDON: Arithmetically, or the  24 underlying data?  25 MR. SACCHET: Arithmetically.</p>
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<p>1 A. That seems to be what it is, yes.  2 Q. That is what it is.  3 A. Okay. Yeah.  4 Q. Your report also states that when applying  5 Albrecht Exhibit 10 and McGovern Exhibit 16, that the  6 p-value -- or that the odds ratio is 2.76 when using  7 Fisher's exact; correct?  8 A. Well that -- that -- yeah. And that --  9 that's not --  10 The -- the test, the Fisher's exact, has to  11 do with the p-value, not the -- not the estimate of  12 what the odds ratio is.  13 Q. So on page two of your report when you say  14 the odds ratio for this comparison is 2.76, where did  15 you get that from?  16 A. That's just a cross-product ratio for that  17 table.  18 Q. And is that -- okay.  19 So the 2.76 derives from Albrecht Exhibit 10  20 and McGovern Exhibit 16.  21 A. That's right. It's a tabulation of those  22 data. I mean it's --  23 Yeah.  24 Q. And it's only accurate insofar as those  25 exhibits are accurate; correct?</p>	<p>1 A. Well it's the -- it's the -- two point --  2 Where is that? Oh, here we are. Okay.  3 Yeah. That's based on this -- this table that is the  4 four out of 372 and 31 out of 1065.  5 Q. And where did you get that data?  6 A. That's from -- from --  7 Was it Albrecht 10?  8 Q. Okay. You would agree that that odds ratio  9 is still above 2.0; correct?  10 A. Yes.  11 Q. Would you agree that an odds ratio of 2.0 is  12 often referred to as a doubling of the risk?  13 A. It -- it is, yeah.  14 Q. And -- and that means you're 50 percent more  15 likely to experience the outcome after exposure to the  16 variable than the count as actual?  17 MR. GORDON: Object to the form of the  18 question.  19 A. Well if -- what it would imply, if -- if --  20 if the odds ratio was -- if the --  21 The odds ratio is actually a ratio of odds.  22 The statement that you made as -- is re -- is  23 related -- you state it as a ratio of -- of risks,  24 which would typically mean a ratio of the -- of the  25 incidence rates.</p>

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<p style="text-align: right;">Page 225</p> <p>1 Q. Okay.</p> <p>2 A. So when the incidence rates are small, those</p> <p>3 two are very similar, okay, and so they're roughly</p> <p>4 used in that way. So an odds ratio of two, it's --</p> <p>5 strictly speaking it's twice the odds of getting an</p> <p>6 infection, although it's going to be very close as --</p> <p>7 to -- to twice the incidence.</p> <p>8 Q. Okay.</p> <p>9 A. So if -- well if -- if you're saying that</p> <p>10 the -- the Hot Dog is the norm and the odds ratio is</p> <p>11 two, that would say that the Bair Hugger has twice the</p> <p>12 risk.</p> <p>13 Q. Okay.</p> <p>14 A. That's how -- how you would roughly</p> <p>15 interpret that statement.</p> <p>16 Q. Okay.</p> <p>17 A. Depending on whether or not -- whether that</p> <p>18 statement is correct we might disagree on, but --</p> <p>19 Q. So if the incidence of disease in an exposed</p> <p>20 group is more than twice the incidence in the</p> <p>21 unexposed group, the probability that exposure to the</p> <p>22 agent caused a similarly situated individual is also</p> <p>23 greater than 50 percent; correct?</p> <p>24 A. If -- if that estimate is -- is accurate,</p> <p>25 that's roughly what it would -- what it would be --</p>	<p style="text-align: right;">Page 227</p> <p>1 A. That's right.</p> <p>2 Q. They are two different time periods;</p> <p>3 correct?</p> <p>4 A. That's correct.</p> <p>5 Q. That's an apples-to-orange comparison; isn't</p> <p>6 it?</p> <p>7 MR. GORDON: Object to the form of the</p> <p>8 question.</p> <p>9 Q. Let me put it this way: It's not externally</p> <p>10 generalizable.</p> <p>11 A. It's not --</p> <p>12 What do you mean?</p> <p>13 Q. It's not externally valid. I mean if -- if</p> <p>14 you're looking at a date range of 2010 to 2015, you</p> <p>15 don't know for sure whether that --</p> <p>16 A. Yeah.</p> <p>17 Q. -- infection rate should apply to prior</p> <p>18 years; do you?</p> <p>19 A. Well if -- if things are reasonably --</p> <p>20 I mean the -- the assumption there is that</p> <p>21 there's not a huge temporal trend going on in</p> <p>22 infection rates in the U.K., and so my -- my</p> <p>23 assumption is -- I -- I didn't have --</p> <p>24 Ideally, I would have had the data for the</p> <p>25 same years. I didn't.</p>
<p style="text-align: right;">Page 226</p> <p>1 what it -- what it would mean.</p> <p>2 Q. Thank you.</p> <p>3 Okay. I'd like to talk a little bit about</p> <p>4 the other section of your report which deals with the</p> <p>5 time trend infection rates at Wansbeck, and I guess</p> <p>6 really the -- the big header is "Infection rate</p> <p>7 comparison among hospitals" starting on page three, at</p> <p>8 the bottom of page three, and then continuing into</p> <p>9 four and five.</p> <p>10 So to be clear, in your report you note that</p> <p>11 there is a .6 percent infection rate among NHS trust</p> <p>12 in 2010 to 2015; correct?</p> <p>13 A. Yes.</p> <p>14 Q. And when you cite a 2.9 percent infection</p> <p>15 rate at the top of page four, that is based also on</p> <p>16 the Albrecht Exhibit 10 and McGovern Exhibit 16 data;</p> <p>17 correct?</p> <p>18 A. That's right.</p> <p>19 Q. And to be clear, that infection rate as it</p> <p>20 relates to Bair Hugger patients was during the 2008</p> <p>21 and 2009 time period; correct?</p> <p>22 A. That's correct.</p> <p>23 Q. So you are comparing an infection rate of</p> <p>24 Bair Hugger patients in 2008 and 2009 to an infection</p> <p>25 rate from 2010 to 2015.</p>	<p style="text-align: right;">Page 228</p> <p>1 Q. Okay.</p> <p>2 A. And so I used the best data that I could get</p> <p>3 ahold of to -- to see what the experience was at other</p> <p>4 hospitals using Bair Hugger at this time to get a</p> <p>5 comparison of how Wansbeck fit -- fit in with the --</p> <p>6 with the experience at other hospitals.</p> <p>7 Q. Did you try to get data from 2008 to 2009?</p> <p>8 A. I didn't have -- I didn't have a -- didn't</p> <p>9 come across a good way of doing that.</p> <p>10 Q. Okay. But you recognize that it's two</p> <p>11 different time periods.</p> <p>12 A. Yes, I do. Uh-huh.</p> <p>13 Q. Are you aware of infection rates in the</p> <p>14 United States as opposed to infection rates reported</p> <p>15 by the NHS in the U.K.?</p> <p>16 A. No. I don't know what the rates are in the</p> <p>17 U.S.</p> <p>18 Q. So you do not know whether the rates of</p> <p>19 infection as reported in the McGovern study are</p> <p>20 comparable to rates in the United States.</p> <p>21 A. I don't have a direct es -- estimate of</p> <p>22 rates in the United States. My assumption is that</p> <p>23 they're not too different, but --</p> <p>24 Q. But --</p> <p>25 A. -- I don't know. I don't have the data.</p>

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<p>1       <b>A. That's -- that's -- that's what he reported.</b></p> <p>2       Q. Are you aware that Dr. Reed also testified</p> <p>3       that to rely on data prior to July 1st, 2008 would be,</p> <p>4       quote, very unreliable, end quote?</p> <p>5       <b>A. That's what he reported.</b></p> <p>6       <b>I mean related to this, I mean there's a --</b></p> <p>7       <b>there was a review of -- of the procedures that they</b></p> <p>8       <b>were using that's referred to in one of the other</b></p> <p>9       <b>papers --</b></p> <p>10       <b>What is the author? Starts with a G.</b></p> <p>11       <b>Gissell?</b></p> <p>12       Q. Gillson.</p> <p>13       <b>A. Gillson. Thank you.</b></p> <p>14       <b>-- that this was all not reviewed until</b></p> <p>15       <b>December, so I'm not sure where -- what Reed is</b></p> <p>16       <b>referring to.</b></p> <p>17       Q. So you don't believe Dr. Reed's testimony</p> <p>18       that full surveillance began on Septem -- on July 1st,</p> <p>19       2008.</p> <p>20       <b>A. Well he's -- he's depending on his</b></p> <p>21       <b>recollection, --</b></p> <p>22       Q. Okay.</p> <p>23       <b>A. -- I assume, in his deposition.</b></p> <p>24       Q. Uh-huh.</p> <p>25       <b>A. And I mean that's what he's -- what -- what</b></p>	<p>1       <b>provided. These were the data that I had available to</b></p> <p>2       <b>me.</b></p> <p>3       Q. But --</p> <p>4       So I just want to be clear. Based on what</p> <p>5       you just said, it's either possible that full</p> <p>6       surveillance began on July 1st, 2008 or --</p> <p>7       <b>A. Yes.</b></p> <p>8       Q. -- perhaps even January 1st, 2009, --</p> <p>9       <b>A. So what --</b></p> <p>10       <b>Yeah.</b></p> <p>11       Q. -- but you nonetheless constructed your</p> <p>12       model on data that was prior to that time; correct?</p> <p>13       <b>A. That's -- that's right.</b></p> <p>14       Q. And that data --</p> <p>15       <b>A. And --</b></p> <p>16       Q. -- may or may not be complete.</p> <p>17       <b>A. And --</b></p> <p>18       Q. Answer the question, please.</p> <p>19       <b>A. Well according to Reed's testimony, if</b></p> <p>20       <b>Reed's correct, if -- if -- if this is correct, that</b></p> <p>21       <b>might be true.</b></p> <p>22       Q. Okay.</p> <p>23       <b>A. The other thing that's true, then, if that's</b></p> <p>24       <b>what in fact took place, is that six months -- or</b></p> <p>25       <b>whatever it is -- six months or so of McGovern is not</b></p>
Page 246	Page 248
<p>1       <b>he said in his -- in his deposition; however, that</b></p> <p>2       <b>seems to not correspond in a peer-reviewed paper what</b></p> <p>3       <b>was said about when this was all reviewed.</b></p> <p>4       Q. So is your statement that in the Gillson</p> <p>5       article the authors there represented that the full</p> <p>6       surveillance began in December of 2008?</p> <p>7       <b>A. It was reviewed in December.</b></p> <p>8       Q. Reviewed in December. But you have no</p> <p>9       knowledge --</p> <p>10       <b>A. I don't --</b></p> <p>11       Q. -- as to whether --</p> <p>12       <b>A. It doesn't say when it was implemented, --</b></p> <p>13       Q. Okay.</p> <p>14       <b>A. -- but that would imply, if it was not</b></p> <p>15       <b>reviewed until December, that it would have been not</b></p> <p>16       <b>implemented until maybe January. Right? I mean if</b></p> <p>17       <b>it's not --</b></p> <p>18       Q. January '09?</p> <p>19       <b>A. '09. Yeah.</b></p> <p>20       Q. Okay. So if full surveillance wasn't</p> <p>21       implemented until January '09, --</p> <p>22       <b>A. Yes.</b></p> <p>23       Q. -- you're relying on data from July -- prior</p> <p>24       to July 2008.</p> <p>25       <b>A. These were the data that were -- were</b></p>	<p>1       <b>reporting appropriately.</b></p> <p>2       Q. So if this document from the NHS says that</p> <p>3       since July 2008 hospitals are required to have sys --</p> <p>4       systems in place to identify patients who are included</p> <p>5       in the surveillance and later admitted to hospitals</p> <p>6       with an SSI, would that clarify any doubt as to when</p> <p>7       full surveillance began in the NHS?</p> <p>8       MR. GORDON: Object to the form of the</p> <p>9       question, lack of foundation.</p> <p>10       <b>A. Well there is --</b></p> <p>11       <b>I mean you're -- you're raising questions</b></p> <p>12       <b>about how accurate the data were recorded, but I mean</b></p> <p>13       <b>all of these change -- changes took place during the</b></p> <p>14       <b>McGovern study.</b></p> <p>15       Q. If Mr. Reed's testimony is true -- if Dr.</p> <p>16       Reed's testimony is true --</p> <p>17       MR. SACCHET: I just said "mister,"</p> <p>18       but I --</p> <p>19       (Discussion off the stenographic record.)</p> <p>20       Q. Okay. If Mr. Reed's testimony is that full</p> <p>21       surveillance began on July 1st, 2008, that is the</p> <p>22       start of the Bair Hugger period in the McGovern study;</p> <p>23       correct?</p> <p>24       <b>A. That's --</b></p> <p>25       <b>According to his deposition, that -- that's</b></p>

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<p>1 you used Albrecht 10, based on the uncontrolled</p> <p>2 calculation, was 2.76; correct?</p> <p>3 <b>A. That's correct.</b></p> <p>4 Q. The decrease in the odds ratio is .6;</p> <p>5 correct?</p> <p>6 <b>A. That's right.</b></p> <p>7 Q. So that would be at best the magnitude of</p> <p>8 the degree of confounding if there is any confounding,</p> <p>9 correct, based on your calculation?</p> <p>10 <b>A. Yeah. Well that -- that -- that change</b></p> <p>11 <b>would be a change due to controlling for --</b></p> <p>12 <b>controlling for use -- use of this -- of -- of this --</b></p> <p>13 <b>of this treatment, whatever that corresponds to.</b></p> <p>14 Q. But I want to be clear that the change is .6</p> <p>15 in the odds ratio; correct?</p> <p>16 <b>A. That's right. That's right.</b></p> <p>17 Q. In your response to Mantel you say that the</p> <p>18 inference on the disease factor association was quite</p> <p>19 different when one controlled for age with respect to</p> <p>20 cancer; correct?</p> <p>21 <b>A. It depended --</b></p> <p>22 <b>I don't know what the example was here.</b></p> <p>23 Q. Okay. Would you --</p> <p>24 <b>A. Whatever it is.</b></p> <p>25 Q. -- view a change of .6 to be quite</p>	<p>1 Q. This odds -- this odds ratio is still above</p> <p>2 2.0 --</p> <p>3 <b>A. It is.</b></p> <p>4 Q. -- when controlling for the</p> <p>5 thromboprophylaxis; correct?</p> <p>6 <b>A. That's right.</b></p> <p>7 Q. There is still a doubling of the risk even</p> <p>8 when controlling for the thromboprophylaxis; correct?</p> <p>9 <b>A. That's right. So --</b></p> <p>10 Q. Okay.</p> <p>11 <b>A. -- if you --</b></p> <p>12 <b>You're looking at a difference at -- at the</b></p> <p>13 <b>change above one, --</b></p> <p>14 Q. Okay.</p> <p>15 <b>A. -- not -- not zero.</b></p> <p>16 Q. But you would still agree that the --</p> <p>17 <b>A. It's a fairly big chart -- change.</b></p> <p>18 Q. -- the change --</p> <p>19 The controlled thromboprophylaxis OR is</p> <p>20 still above 2.0.</p> <p>21 <b>A. It is, yes.</b></p> <p>22 Q. And it --</p> <p>23 That means it's still a doubling of the risk</p> <p>24 even when the thrombo --</p> <p>25 <b>A. But the point -- the point estimate is</b></p>
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<p>1 different?</p> <p>2 <b>A. I'd say it's a fair -- fair difference, yes.</b></p> <p>3 Q. Okay.</p> <p>4 <b>A. So 2. -- 2.76, yeah, I mean that's --</b></p> <p>5 <b>it's --</b></p> <p>6 Q. Approximately 20 percent.</p> <p>7 <b>A. Oh, it's more than 26 percent; isn't it?</b></p> <p>8 <b>It's --</b></p> <p>9 Q. I don't think so.</p> <p>10 <b>A. -- two --</b></p> <p>11 Q. .6 --</p> <p>12 <b>A. -- point --</b></p> <p>13 Q. -- on 2.76?</p> <p>14 <b>A. Well the 2.76, that's a -- an increase of</b></p> <p>15 <b>1.76.</b></p> <p>16 Q. From 2.76 to 2.16 is a difference of .6.</p> <p>17 <b>A. Right.</b></p> <p>18 Q. Okay.</p> <p>19 <b>A. And so if there's no association, the odds</b></p> <p>20 <b>ratio is -- is -- is one.</b></p> <p>21 Q. You're getting that from controlling both --</p> <p>22 <b>A. If there's no -- no association, you're</b></p> <p>23 <b>looking at --</b></p> <p>24 Q. Correct.</p> <p>25 <b>A. -- the ratio of two incidence rates.</b></p>	<p>1 <b>above. I mean look at the confidence limits.</b></p> <p>2 Q. Of your calculation?</p> <p>3 <b>A. .7 --</b></p> <p>4 <b>After you control for it.</b></p> <p>5 Q. Yes.</p> <p>6 <b>A. .73 to 8. --</b></p> <p>7 <b>I mean it's still --</b></p> <p>8 Q. It's --</p> <p>9 <b>A. The estimate of what the effect is is not</b></p> <p>10 <b>very precise I would say.</b></p> <p>11 Q. It's a third of the size of your Jensen</p> <p>12 reanalysis; is it not? Your Jensen reanalysis has as</p> <p>13 25-point confidence interval.</p> <p>14 <b>A. The 25, that's --</b></p> <p>15 Q. One to 25.</p> <p>16 MR. GORDON: Object to the form of the</p> <p>17 question, assumes facts not in evidence.</p> <p>18 <b>A. Yeah. I -- you're looking at --</b></p> <p>19 <b>I mean those are not a fair comparison. I</b></p> <p>20 <b>mean --</b></p> <p>21 Q. Why not?</p> <p>22 <b>A. I mean both of them are very poor estimates.</b></p> <p>23 Q. Yours is three times the size --</p> <p>24 <b>A. Well you're looking at the range.</b></p> <p>25 Q. -- of this.</p>

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<p style="text-align: right;">Page 293</p> <p>1       <b>A. Remember, I said, you know, the -- when you</b>  2       <b>construct a confidence interval on an odds ratio, you</b>  3       <b>generally do it on the log transformation, --</b>  4       Q. Okay.  5       <b>A. -- and so once you threw it -- do it in the</b>  6       <b>log, you have to look at it in the log scale.</b>  7       Q. Okay. You would agree, nonetheless, that  8       the odds -- that the confidence interval you  9       calculated based on the Jensen reanalysis is larger  10      than the confidence interval of both the McGovern  11      study and the confidence interval that you report when  12      controlling for the thromboprophylaxis.  13      <b>A. The range of the two would be greater, yes,</b>  14      <b>the range of the two would be greater, but a big part</b>  15      <b>of that reason for the change in the range, the</b>  16      <b>arithmetic difference in that range, is because the</b>  17      <b>odds ration is much smaller. In the other example in</b>  18      <b>the -- in the -- from the -- from the Jensen</b>  19      <b>comparison, the odds ratio was 4.77.</b>  20      Q. Okay.  21      <b>A. So that's more than twice --</b>  22      Q. Okay.  23      <b>A. -- what the odds ratio is here.</b>  24      Q. Your odds ratio is more than three times the  25      ev -- the confidence interval here. Your confidence</p>	<p style="text-align: right;">Page 295</p> <p>1       <b>A. No.</b>  2       Q. So you haven't reviewed any published  3       literature regarding the safety of Xarelto with  4       respect to deep joint infection.  5       MR. GORDON: Objection, asked and answered.  6       <b>A. No, I've --</b>  7       Q. Are you going to publish it?  8       <b>A. No.</b>  9       Q. So there is no published literature that you  10      are aware of that suggests a relationship between the  11      variable of a thromboprophylaxis on the outcome of  12      deep joint infection.  13      <b>A. I don't know of any.</b>  14      Q. Okay. If we could, let me show you another  15      document.  16      <b>A. I mean it is interesting that they in</b>  17      <b>fact -- they seem to have not --</b>  18      <b>They went -- they went back to using the --</b>  19      <b>using the treatment they were originally using even</b>  20      <b>though the Jensen paper did not find it statistically</b>  21      <b>significant.</b>  22      Q. You don't have an ex -- expertise in  23      infectious disease; do you?  24      <b>A. No.</b>  25      Q. You're not a medical doctor.</p>
<p style="text-align: right;">Page 294</p> <p>1       interval is three times the size of the confidence  2       interval even though the odds ratio here is half the  3       amount of the odds ratio you reported --  4       <b>A. Yes. Okay.</b>  5       Q. -- in the Jensen reanalysis.  6       <b>A. Okay.</b>  7       Q. Okay.  8       <b>A. So I don't -- I don't -- I don't understand</b>  9       <b>what your point is. But --</b>  10      Q. My point is that it's clear that the Jensen  11      reanalysis has more variability than does your  12      calculation of the 2.16 odds ratio --  13      <b>A. The difference between the high and low --</b>  14      Q. -- when controlling for the  15      thromboprophylaxis; correct?  16      <b>A. The difference be -- the -- the --</b>  17      <b>The difference between the high and the low</b>  18      <b>of the confidence interval is greater on that one</b>  19      <b>than -- is -- is diff -- quite different between those</b>  20      <b>two. I agree to that.</b>  21      Q. It's greater.  22      <b>A. It's greater. I agree with that.</b>  23      Q. Thank you.  24      As to the Jensen reanalysis, have you  25      published your reanalysis of the Jensen study?</p>	<p style="text-align: right;">Page 296</p> <p>1       <b>A. I'm not.</b>  2       Q. You don't know why they changed back to  3       tinzaparin.  4       <b>A. No, I -- no, I don't. I don't know if this</b>  5       <b>is the basis of it or not.</b>  6       Q. Okay.  7       <b>A. But I mean this was the ba --</b>  8       <b>It was Jensen's paper that -- that McGovern</b>  9       <b>is quoting, right, --</b>  10      Q. Uh-huh.  11      <b>A. -- as the -- as for saying why it's not a</b>  12      <b>confounder?</b>  13      Q. And the Jensen --  14      <b>A. And while the Jensen paper is not -- not</b>  15      <b>statistically significant, --</b>  16      Q. Uh-huh.  17      <b>A. -- they nevertheless changed the policy --</b>  18      <b>changed the regimen that they were using at Wansbeck.</b>  19      Q. Okay. But you don't know why they did.  20      <b>A. No, I don't.</b>  21      Q. Okay.  22      <b>A. I find it interesting.</b>  23      Q. Did you ask anyone why they changed from  24      tinzaparin to Xarelto and back to tinzaparin?  25      <b>A. No.</b></p>

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<p style="text-align: right;">Page 301</p> <p>1 Q. Are you aware that the record studies found</p> <p>2 that Xarelto is not related to infection?</p> <p>3 MR. GORDON: Objection, asked and answered,</p> <p>4 lack of foundation.</p> <p>5 A. I think I said I had not looked at the</p> <p>6 record studies.</p> <p>7 Q. Would it be helpful to look at one?</p> <p>8 A. I mean I -- it --</p> <p>9 When I was looking within the Albright 10</p> <p>10 data set, I found the association that I reported.</p> <p>11 Now I think the premise of your question is: Is the</p> <p>12 association that I found, is that a causal association</p> <p>13 or not? The way this study was designed, is this</p> <p>14 temporal? You know, these time periods are changing.</p> <p>15 And as I show in Fig. 2 --</p> <p>16 Q. Okay.</p> <p>17 A. -- show in Fig. 2 and I present the --</p> <p>18 related to that I show in figure -- I'm sorry, on</p> <p>19 page -- ah, where is that? On page four, the last</p> <p>20 paragraph, it compares the infection rates by</p> <p>21 quarter --</p> <p>22 Q. Yeah.</p> <p>23 A. -- and we got a chi-square of 15.5 on six</p> <p>24 degrees of freedom, p-value of .0167. So what that</p> <p>25 suggests is that the incidence rates during the Bair</p>	<p style="text-align: right;">Page 303</p> <p>1 what, two and a half times as much variability as what</p> <p>2 I would expect to see if the only variation that was</p> <p>3 taking place was just a random fluctuation based on,</p> <p>4 you know, what's going on with the use of -- of -- of</p> <p>5 these surgical procedures at Wansbeck.</p> <p>6 Q. You didn't do that calculation with respect</p> <p>7 to the reanalysis of the Jensen data; correct?</p> <p>8 A. I -- I didn't -- I didn't allow for random</p> <p>9 variability other than the binomial variability --</p> <p>10 Q. Okay.</p> <p>11 A. -- that -- that we assumed. No, I -- I took</p> <p>12 that at a face value. And -- and it could be random.</p> <p>13 My assumption is it's not random. My assumption is</p> <p>14 it's due to other factors that are -- that were</p> <p>15 affecting risk at Wansbeck during this time period.</p> <p>16 Q. That's an assumption.</p> <p>17 A. It is.</p> <p>18 Q. Okay. I want to go back to the -- what we</p> <p>19 were talking about with respect --</p> <p>20 Did you do any investigation to determine</p> <p>21 whether your assumption was correct or not?</p> <p>22 A. I -- I have no further --</p> <p>23 I have not been in contact with Wansbeck or</p> <p>24 anyone else involved with this to know that for</p> <p>25 certain. I guess a part of my -- my -- my reasons for</p>
<p style="text-align: right;">Page 302</p> <p>1 Hugger period were changing quite a lot, and those</p> <p>2 differences were statistically significant.</p> <p>3 Q. Okay.</p> <p>4 A. So this is not a period where things were</p> <p>5 just under well controlled.</p> <p>6 Q. Are you aware of whether deep joint</p> <p>7 infections are always constant or whether there is</p> <p>8 variability in deep joint infections more generally?</p> <p>9 A. Well if there is variability more generally,</p> <p>10 then that needs to be taken into account in the</p> <p>11 analysis, and this analysis does not do that.</p> <p>12 Q. When you conducted --</p> <p>13 A. I did not do that, and McGovern certainly</p> <p>14 didn't do it either.</p> <p>15 Q. When you construct a statistical model, the</p> <p>16 confidence interval accounts for the variance of the</p> <p>17 data; correct?</p> <p>18 A. Well it should. But the confidence</p> <p>19 intervals that I computed and the confidence intervals</p> <p>20 that McGovern computed don't take that -- that</p> <p>21 variability into account.</p> <p>22 Q. Okay.</p> <p>23 A. The expected value of this chi-square</p> <p>24 statistic is equal to the degrees of freedom, so you</p> <p>25 expect it to be six, in fact it's 15.5, so there's,</p>	<p style="text-align: right;">Page 304</p> <p>1 thinking there were other things going on is the</p> <p>2 Gillson paper, for example, enumerates such a huge</p> <p>3 array of things that were taking place at -- what is</p> <p>4 it -- Northumbria group of hospitals, --</p> <p>5 Q. Okay.</p> <p>6 A. -- so they were having a problem.</p> <p>7 Obviously, NHS was -- was calling them on having a</p> <p>8 high infection rate that they needed to do something</p> <p>9 about, and the -- the Gissell paper elaborates on all</p> <p>10 the things that they were trying to do to bring this</p> <p>11 thing under control, and there were a lot of other</p> <p>12 things other than switching to Hot Dog.</p> <p>13 Q. Okay. Did you ask 3M for any info with</p> <p>14 respect to this issue?</p> <p>15 A. No.</p> <p>16 MR. GORDON: Object to the form of the</p> <p>17 question.</p> <p>18 Q. Okay. Are you aware that in the Gillson</p> <p>19 article the descriptor for infection is SSI?</p> <p>20 MR. GORDON: Object to the form of the</p> <p>21 question.</p> <p>22 Q. The title of the article is SSI.</p> <p>23 A. Which paper are you talking about?</p> <p>24 Q. You just referenced the Gillson article, --</p> <p>25 A. Gillson, okay.</p>

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<p>1 Q. -- "Implementing Effective SSI Measures."  2 A. <b>Right. Yes.</b>  3 Q. Do you know what "SSI" stands for?  4 A. <b>Ahh, oh --</b>  5 <b>I've forgotten.</b>  6 Q. Surgical-site infection ring a bell?  7 A. <b>Surgical-site infection. Exactly, yeah.</b>  8 Q. Surgical-site infections are not the same  9 thing as deep joint infections.  10 MR. GORDON: Object to the form of the  11 question, lack of foundation, misconstrues the  12 evidence and assumes facts not in evidence.  13 Q. Do you know whether an SSI is the same as a  14 DJI?  15 MR. GORDON: Same objection.  16 A. <b>It's -- it's not the same, it's not the same</b>  17 <b>thing. They are -- they would be --</b>  18 <b>Are you saying -- suggesting they are not</b>  19 <b>related?</b>  20 Q. I'm suggesting that --  21 Do you know whether the measures that were  22 implemented in the Northumbria trust were specific to  23 SSI or DJI?  24 A. <b>I think --</b>  25 <b>Well the paper is entitled for SSI.</b></p>	<p>1 <b>But I -- I believe that they would be</b>  2 <b>related to each other. And things that you're doing</b>  3 <b>to control SSI, my understanding is you would have --</b>  4 <b>you would have effects on -- on PJI as well.</b>  5 Q. What's your understanding based on?  6 A. <b>Well looking at -- well I mean the -- one --</b>  7 <b>This is from the -- from the Gillson paper.</b>  8 Q. What is?  9 A. <b>A patient with a -- with a -- with surgery</b>  10 <b>on his knee.</b>  11 Q. Do you see the implant?  12 A. <b>I see the surgery on his knee.</b>  13 Q. Do you know whether that would result in  14 either a superficial wound infection on the skin or  15 whether it would result in a deep infection on a  16 prosthetic?  17 A. <b>I don't know. If it was a deep infection, I</b>  18 <b>think that would be something they would -- they would</b>  19 <b>be interested in.</b>  20 <b>You don't think that -- you don't think they</b>  21 <b>would be interested in that as -- as respect to the</b>  22 <b>surgery?</b>  23 Q. Are you asking me?  24 A. <b>Yeah.</b>  25 Q. I'm --</p>
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<p>1 Q. So you don't know whether they were specific  2 to deep joint infection.  3 A. <b>Well I would assume that they would -- they</b>  4 <b>would be effective on affecting both. I mean</b>  5 <b>orthopedic surgery appears to be one of the things</b>  6 <b>that they are in fact looking at.</b>  7 Q. Can you define SSI?  8 A. <b>I don't know the --</b>  9 <b>I don't know. I'm -- it's not a -- an area</b>  10 <b>that I've particularly done -- done work -- work on.</b>  11 <b>I --</b>  12 Q. Can you define DJI?  13 A. <b>It's -- it's again the --</b>  14 <b>It's joint -- joint infections --</b>  15 Q. Okay.  16 A. <b>-- that -- that you're looking at.</b>  17 Q. But you have no scientific basis or  18 expertise to conclude whether or not the inter --  19 interventions that are mentioned in the Gillson  20 article which relate to SSI would have an impact on  21 deep joint infection; correct?  22 A. <b>It's --</b>  23 <b>They're not areas that I have -- that I</b>  24 <b>have -- that I have personally done research on.</b>  25 <b>My -- my --</b></p>	<p>1 <b>A. I mean you -- you seem to be suggesting that</b>  2 <b>there's no effect. Why -- why what you're asking</b>  3 <b>me --</b>  4 Q. I would let --  5 Your -- your report concludes that the SSI  6 bundle may have had an effect on deep joint infection  7 rates; correct?  8 A. <b>Yes. The things that they were doing to</b>  9 <b>control SSI may have had an effect.</b>  10 Q. You have no scientific basis to make that  11 conclusion.  12 A. <b>I'm -- no, no. I'm just -- just assuming</b>  13 <b>that it does.</b>  14 Q. Thank you.  15 Do you know if any articles that you're  16 relying on relate to SSI versus DJI?  17 A. <b>No.</b>  18 Q. So you're not sure whether the publications  19 that you've cited on page 14 of your report are  20 specific to deep joint infection or a surgical-site  21 infection.  22 A. <b>Oh. Some of them --</b>  23 <b>I'm not sure which articles you're -- you're</b>  24 <b>talking about.</b>  25 Q. Well do you know offhand? I don't want to</p>

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<p style="text-align: right;">Page 313</p> <p>1 infection rates?</p> <p>2 <b>A. Other than the -- the analysis that I did</b></p> <p>3 <b>using Albrecht 10, that -- that's basically what I was</b></p> <p>4 <b>using.</b></p> <p>5 Q. In your report you assume that the</p> <p>6 thromboprophylaxis may be a confounding factor, but</p> <p>7 you never state as much with respect to the</p> <p>8 antibiotic; is that true?</p> <p>9 <b>A. I don't know if I stated it. It is -- it is</b></p> <p>10 <b>potentially a -- a -- a confounding variable and in</b></p> <p>11 <b>fact I did adjust for it in -- I did present an</b></p> <p>12 <b>analysis where I adjusted for it.</b></p> <p>13 Q. So did you adjust for the antibiotic without</p> <p>14 considering whether it was a confounding factor?</p> <p>15 <b>A. Well, I mean whether it's a confounding</b></p> <p>16 <b>factor, as I -- as I said before, it -- it depends on</b></p> <p>17 <b>whether -- whether there is a change in the --</b></p> <p>18 <b>It affects the -- the association.</b></p> <p>19 Q. Okay.</p> <p>20 <b>A. And in this case the association -- let's</b></p> <p>21 <b>see.</b></p> <p>22 <b>When we just controlled for the</b></p> <p>23 <b>thromboprophylaxis --</b></p> <p>24 Q. I think we're on the antibiotic.</p> <p>25 <b>A. Yes. When we just controlled for -- for</b></p>	<p style="text-align: right;">Page 315</p> <p>1 MR. GORDON: On page six.</p> <p>2 Q. It's on page six.</p> <p>3 <b>A. Oh, I'm sorry.</b></p> <p>4 Q. Right under the heading "Comparison of the</p> <p>5 effect of antibiotic regimen on study results." And</p> <p>6 you report that there was a rate of infection during</p> <p>7 the Bair Hugger period when Gentamicin was used of</p> <p>8 1.92 percent; correct?</p> <p>9 <b>A. Oh, okay. This is --</b></p> <p>10 <b>Yeah. We were -- I think we were talking</b></p> <p>11 <b>about two different things. This is, I think, just</b></p> <p>12 <b>looking at the effect of an antibiotic on --</b></p> <p>13 Q. Yes.</p> <p>14 <b>A. Yeah.</b></p> <p>15 Q. Okay.</p> <p>16 <b>A. I was talking about controlling for it.</b></p> <p>17 <b>Yeah.</b></p> <p>18 Q. Okay. So here we essentially controlled for</p> <p>19 the use of the Bair Hugger and viewed infection rates</p> <p>20 when Gentamicin was applied versus when Gentamicin</p> <p>21 plus Teicoplanin was applied; correct?</p> <p>22 <b>A. That's right. Because it's only during</b></p> <p>23 <b>the --</b></p> <p>24 Q. Yeah.</p> <p>25 <b>A. -- Bair Hugger.</b></p>
<p style="text-align: right;">Page 314</p> <p>1 <b>the -- for the thromboprophylaxis, the -- the odds</b></p> <p>2 <b>ratio was, what, 2.49? Is that right? No, I'm sorry,</b></p> <p>3 <b>2.16.</b></p> <p>4 Q. That's the odds ratio for controlling for</p> <p>5 the thromboprophylaxis; correct?</p> <p>6 <b>A. From -- from --</b></p> <p>7 <b>Yes, right.</b></p> <p>8 Q. And we're talking about the antibiotic.</p> <p>9 <b>A. And then so now when we add, in addition to</b></p> <p>10 <b>controlling for the thromboprophylaxis we're adding</b></p> <p>11 <b>the antibiotic, which is what you were asking about --</b></p> <p>12 Q. Well I actually wasn't asking about that.</p> <p>13 I'm asking for just with respect to the antibiotic,</p> <p>14 not controlling for both, just controlling for the</p> <p>15 antibiotic. You did that calculation prior to the</p> <p>16 double control; correct?</p> <p>17 <b>A. I don't know that I did the single control.</b></p> <p>18 Q. Okay.</p> <p>19 <b>A. I looked -- I looked --</b></p> <p>20 <b>I did a double control.</b></p> <p>21 Q. You don't recall doing a single control on</p> <p>22 the antibiotic?</p> <p>23 <b>A. I don't think I did.</b></p> <p>24 Q. Well you did.</p> <p>25 <b>A. Oh, I did? Okay.</b></p>	<p style="text-align: right;">Page 316</p> <p>1 Q. Yeah.</p> <p>2 <b>A. Sure.</b></p> <p>3 Q. And protocol one, which we'll call the</p> <p>4 Gentamicin administration, resulted in an infection</p> <p>5 rate of 1.92 percent in patients; correct?</p> <p>6 <b>A. Yes.</b></p> <p>7 Q. Okay. And then protocol two, when</p> <p>8 Gentamicin plus Teicoplanin was used, the rate went up</p> <p>9 to 3.13; correct?</p> <p>10 <b>A. That's right.</b></p> <p>11 Q. That's an increase in the infection rate;</p> <p>12 correct?</p> <p>13 <b>A. Yes.</b></p> <p>14 Q. And that's the combination of antibiotics</p> <p>15 that was used during the Hot Dog period; correct?</p> <p>16 <b>A. Yes.</b></p> <p>17 Q. So actually, the combination of antibiotics</p> <p>18 that was used resulted in a higher infection rate</p> <p>19 between -- compared to the drug that was used with</p> <p>20 just Bair Hugger patients; correct?</p> <p>21 <b>A. That's right.</b></p> <p>22 Q. So if anything --</p> <p>23 <b>A. Yeah. It's the com -- wait.</b></p> <p>24 <b>That's right. Yeah.</b></p> <p>25 Q. Okay.</p>

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<p style="text-align: right;">Page 317</p> <p>1 <b>A. The switchover. Okay. Sorry.</b></p> <p>2 Q. So if anything, there's actually reverse</p> <p>3 confounding in the direction that the use of</p> <p>4 Gentamicin plus Teicoplanin was less effective than</p> <p>5 the use of just Gentamicin; correct?</p> <p>6 <b>A. It appears to be, yes.</b></p> <p>7 Q. So based on that conclusion, the odds ratio</p> <p>8 as reported in the McGovern study could even be higher</p> <p>9 in the event that we controlled for the use of</p> <p>10 Gentamicin plus Teicoplanin; correct?</p> <p>11 <b>A. Well --</b></p> <p>12 Q. You just told me statistical significance</p> <p>13 did not matter.</p> <p>14 MR. GORDON: Object to the form of the</p> <p>15 question, misstates his testimony.</p> <p>16 <b>A. I mean the issue of it being a confounder is</b></p> <p>17 <b>does it affect the association -- does it affect the</b></p> <p>18 <b>measure of association between -- the --</b></p> <p>19 <b>Well, in this case we're looking at Bair</b></p> <p>20 <b>Hugger, Bair Hugger/Hot Dog, does it -- does it affect</b></p> <p>21 <b>that association.</b></p> <p>22 Q. You didn't report an association; did you?</p> <p>23 MR. GORDON: Object to the form of the</p> <p>24 question.</p> <p>25 <b>A. Yeah, it --</b></p>	<p style="text-align: right;">Page 319</p> <p>1 that Gentamicin may be less effective than Gentamicin</p> <p>2 plus Teicoplanin; correct?</p> <p>3 <b>A. It -- it --</b></p> <p>4 <b>The point estimates go in that direction.</b></p> <p>5 <b>It's not --</b></p> <p>6 Q. Okay.</p> <p>7 <b>A. -- statistically significant, --</b></p> <p>8 Q. Okay.</p> <p>9 <b>A. -- although it's --</b></p> <p>10 <b>It's sort of unclear as to whether or not it</b></p> <p>11 <b>does.</b></p> <p>12 Q. With respect to confounding, you previously</p> <p>13 stated that statistical significance is not</p> <p>14 determinant of whether there is confounding; correct?</p> <p>15 <b>A. That's right.</b></p> <p>16 Q. So whether or not the p-value is .1683 does</p> <p>17 not mean that there was reverse confounding with</p> <p>18 respect to the odds ratio reported in the McGovern</p> <p>19 study; correct?</p> <p>20 <b>A. It's -- it --</b></p> <p>21 <b>Well it basically means that it's -- it's --</b></p> <p>22 <b>it's -- it could go either way.</b></p> <p>23 Q. It could --</p> <p>24 <b>A. It's not -- it's not clear.</b></p> <p>25 Q. Okay. And you have not reported an odds</p>
<p style="text-align: right;">Page 318</p> <p>1 Q. Did you report an association with respect</p> <p>2 to controlling for the antibiotic in the Bair Hugger</p> <p>3 arm of the study?</p> <p>4 MR. GORDON: Just the antibiotic?</p> <p>5 MR. SACCHET: Yeah.</p> <p>6 <b>A. Not just the antibiotic, no. That's what I</b></p> <p>7 <b>said, I didn't do that.</b></p> <p>8 Q. You didn't do that.</p> <p>9 <b>A. Look at the effect of --</b></p> <p>10 <b>Well I -- I looked at the effect of -- of</b></p> <p>11 <b>the antibiotic --</b></p> <p>12 Q. Yeah.</p> <p>13 <b>A. -- on risk of infection, --</b></p> <p>14 Q. Okay.</p> <p>15 <b>A. -- and that was this difference of, oh, 1.9</b></p> <p>16 <b>versus 3.1 infection rate with a p-value of .17.</b></p> <p>17 Q. Okay. And the percent of infection when</p> <p>18 using Gentamicin plus Teicoplanin went up compared to</p> <p>19 the use of just Gentamicin; correct?</p> <p>20 <b>A. That's right.</b></p> <p>21 Q. And in the McGovern study, all the Hot Dog</p> <p>22 patients received Gentamicin plus Teicoplanin;</p> <p>23 correct?</p> <p>24 <b>A. Yeah.</b></p> <p>25 Q. This calculation that you performed shows</p>	<p style="text-align: right;">Page 320</p> <p>1 ratio with respect to that calculation; correct?</p> <p>2 <b>A. No, it does --</b></p> <p>3 <b>No, I have not.</b></p> <p>4 Q. So in order to determine whether there was</p> <p>5 reverse confounding or general confounding, you have</p> <p>6 not made the calculation in order to make that</p> <p>7 conclusion; correct?</p> <p>8 <b>A. I haven't said whether or not it's reverse</b></p> <p>9 <b>or --</b></p> <p>10 <b>I'm not -- I'm not sure what -- what you</b></p> <p>11 <b>mean by "reverse" or --</b></p> <p>12 Q. That's what I said, "whether or not." You</p> <p>13 don't know whether there was confounding because you</p> <p>14 haven't reported an odds risk ratio with respect to</p> <p>15 just the control for the antibiotic; correct?</p> <p>16 <b>A. Well it's not just control. I've -- I've</b></p> <p>17 <b>controlled for both antibiotic and thrombo.</b></p> <p>18 Q. I understand. But with respect to</p> <p>19 controlling for the antibiotic in this calculation --</p> <p>20 <b>A. Yes.</b></p> <p>21 Q. -- you report infection rates and you report</p> <p>22 a p-value, you do not report an odds ratio; correct?</p> <p>23 <b>A. That's correct.</b></p> <p>24 Q. There is no way to determine whether the</p> <p>25 odds ratio increased compared to what was provided in</p>

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<p>1 the McGovern study or whether it decreased,  2 correct, --  3 <b>A. Which odds --</b>  4 Q. -- when com --  5 <b>A. -- ratio are you talking about?</b>  6 Q. Either the 3.8 or the 2.76 that you  7 calculated based on Albrecht 10. You have no basis to  8 compare those odds ratios to this calculation.  9 <b>A. Well I compared the odds -- I mean I</b>  10 <b>didn't --</b>  11 <b>I don't report the odds ratio, but you can</b>  12 <b>pretty good -- get a pretty good idea of what -- about</b>  13 <b>what it's going to be --</b>  14 Q. You told me --  15 <b>A. -- because the infection rate -- let's see.</b>  16 <b>"In order to control for the...one must use</b>  17 <b>the Bair Hugger period that -- that shares the</b>  18 <b>antibiotic and thromboprophylaxis regimen used in the</b>  19 <b>Hot Dog period," so -- which had an infection rate of</b>  20 <b>three out of 270, 1.1 percent, and compare that with</b>  21 <b>four out of 372, which is 1.08 percent.</b>  22 Q. You're looking at controlling for both  23 variables, correct, right now?  24 <b>A. That is correct.</b>  25 Q. I want to go back to when you just</p>	<p>1 Q. Yeah. And you haven't done --  2 <b>A. So whether or not it's associated with --</b>  3 <b>Well in this study it -- it certainly is</b>  4 <b>associated with -- with whether or not the Bair Hugger</b>  5 <b>or the Hot Dog was used. In general, who knows?</b>  6 Q. You don't know whether --  7 <b>A. Well --</b>  8 Q. -- the Gentamic --  9 <b>A. -- it depends on what -- what -- what is</b>  10 <b>done by the institution.</b>  11 Q. You don't know whether Gentamicin is more or  12 less effective than Gentamicin plus Teicoplanin --  13 <b>A. Well that's a different question.</b>  14 Q. -- in terms of deep joint infection. That's  15 the question right now. Do you know?  16 <b>A. Well there is the --</b>  17 <b>The analysis based on these data --</b>  18 Q. That shows --  19 <b>A. -- found -- found the -- the result was not</b>  20 <b>statistically significant, the difference of 2.19</b>  21 <b>percent versus 3.1, but -- but --</b>  22 Q. And the infection rate went up with  23 Gentamicin plus Teicoplanin.  24 <b>A. That's right.</b>  25 Q. Okay.</p>
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<p>1 controlled for the antibiotic, which is what we're  2 talking about. You did not provide an odds ratio.  3 <b>A. I did not --</b>  4 <b>That's right, I didn't provide it.</b>  5 Q. You did not determine how or whether the  6 antibiotic by itself is a confounding variable.  7 <b>A. By -- by itself, no. By itself, no.</b>  8 Q. And you have --  9 <b>A. But I've controlled for both of them --</b>  10 Q. We'll get there. I'm just talking about  11 this calculation.  12 You do not know the degree of confounding,  13 if any, caused by only the antibiotic.  14 <b>A. That's right. I didn't do that.</b>  15 Q. And you have not reviewed any literature to  16 suggest that an antibiotic is a confounding factor on  17 deep joint infections.  18 MR. GORDON: Object to the form of the  19 question.  20 <b>A. I don't see -- understand that -- understand</b>  21 <b>your -- your question. To be a confounding variable,</b>  22 <b>as we've said, it has to be associated with -- with</b>  23 <b>the -- with the outcome --</b>  24 Q. Okay.  25 <b>A. -- and the variable you're looking at.</b></p>	<p>1 <b>A. The one -- the one is higher. It's not --</b>  2 <b>That difference is not statistically</b>  3 <b>significant.</b>  4 Q. Okay. Based on that --  5 <b>A. When I -- when I added that into the</b>  6 <b>analysis and controlled for that after I had already</b>  7 <b>controlled from thromboprophylaxis, the -- any</b>  8 <b>association that -- an association that was 2.1 --</b>  9 <b>six was it? -- com -- disappeared effectively</b>  10 <b>completely, I mean 1 -- 1. -- 1.11 percent versus</b>  11 <b>1.08.</b>  12 Q. Okay. Let's talk about --  13 <b>A. So they're basically -- I mean it -- as --</b>  14 <b>It would, I -- I -- I suggest, be an</b>  15 <b>indication that this is a confounding variable because</b>  16 <b>the odds ratio is bas -- basically eliminated.</b>  17 Q. Have you done a powering analysis of this  18 double-control calculation?  19 <b>A. A power analysis, no.</b>  20 Q. You have no idea whether this is adequately  21 powered.  22 <b>A. Oh, it's -- I -- there's --</b>  23 <b>There's never been a power analysis of</b>  24 <b>anything related to McGovern.</b>  25 Q. You don't know whether this calculation --</p>

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<p>1 Samet. It's not --</p> <p>2 That's not my area. I mean we've already</p> <p>3 established what his area is --</p> <p>4 Q. Okay.</p> <p>5 A. -- and this is an area that he feels</p> <p>6 comfortable in and that -- and has -- has -- has done</p> <p>7 work in, and this is not the area --</p> <p>8 Q. You don't feel comfortable in this area.</p> <p>9 A. It's not an area that I -- that I work</p> <p>10 in, --</p> <p>11 Q. Okay.</p> <p>12 A. -- no.</p> <p>13 Q. And so you're unclear about what the</p> <p>14 mechanism of infection that is the issue with respect</p> <p>15 to blowing air in the operating theater; is -- is</p> <p>16 that -- is that your testimony?</p> <p>17 MR. GORDON: Object to the form of the</p> <p>18 question.</p> <p>19 A. It's --</p> <p>20 I mean the authors of this report are</p> <p>21 obviously concerned about blowing -- you know, blowing</p> <p>22 air over water that's -- water that's infected.</p> <p>23 Q. Uh-huh.</p> <p>24 A. I don't know enough about the mechanism of</p> <p>25 the Bair Hugger --</p>	<p>1 con -- conclusions are about -- about causal</p> <p>2 inference.</p> <p>3 Q. Okay.</p> <p>4 A. It was basically the strength --</p> <p>5 Q. Uh-huh.</p> <p>6 A. -- in terms of not only the magnitude of the</p> <p>7 effect, but in terms of the design that was used</p> <p>8 and -- to -- to find those -- those associations and</p> <p>9 whether that is -- the strength of that evidence is --</p> <p>10 was enough to demonstrate a causal -- a causal</p> <p>11 association.</p> <p>12 Q. Do you agree with the statement from The</p> <p>13 Reference Manual on Statistics that "In the end,</p> <p>14 deciding whether associations are causal typically is</p> <p>15 not a matter of statistics alone, but also rests on</p> <p>16 scientific judgment?"</p> <p>17 A. Yes.</p> <p>18 Q. You've only considered the statistical</p> <p>19 aspects; correct?</p> <p>20 A. Well I tried to consider the -- the other</p> <p>21 aspects of -- of the -- of the study as well.</p> <p>22 Q. You said you have no expertise and have not</p> <p>23 delved into the literature as to those additional</p> <p>24 topics; correct?</p> <p>25 A. Of the associated -- of things related</p>
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<p>1 Q. Yeah.</p> <p>2 A. -- to know exactly what is --</p> <p>3 Is there a pool of water in the Bair Hugger</p> <p>4 that it -- that it's blowing air over?</p> <p>5 Q. Okay.</p> <p>6 A. I don't know.</p> <p>7 Q. So you've opined about whether one can draw</p> <p>8 a causal inference as to whether the Bair Hugger</p> <p>9 increases the risk of infection, but you don't</p> <p>10 understand the ways in which the Bair Hugger might in</p> <p>11 fact result in an increase in infection.</p> <p>12 MR. GORDON: Object to the form of the</p> <p>13 question, misstates his testimony.</p> <p>14 A. I think -- I think that's not -- not an</p> <p>15 accurate description of what -- what I've -- what I've</p> <p>16 been saying. I was looking at the -- the evidence for</p> <p>17 a causal -- a causal association --</p> <p>18 Q. Uh-huh.</p> <p>19 A. -- and does -- that has in -- that has</p> <p>20 basically involved looking at what the -- the design</p> <p>21 and the estimates of effect that were known to me</p> <p>22 at the -- at the time that I did that -- did that</p> <p>23 analysis.</p> <p>24 Q. And that's it.</p> <p>25 A. And that's basically what I was drawing my</p>	<p>1 specifically to these devices. I was primarily</p> <p>2 concentrating on the studies that had been done on the</p> <p>3 epidemiology.</p> <p>4 Q. And those studies are the McGovern study and</p> <p>5 the Augustine study, which are the only two</p> <p>6 epidemiologic studies on the risk of infection from</p> <p>7 the Bair Hugger to deep joint infection; correct?</p> <p>8 A. For the Bair -- for the Bair Hugger effect,</p> <p>9 the Bair Hugger/Hot Dog comparison, those were the --</p> <p>10 basically the studies that I was comparing.</p> <p>11 MR. SACCHET: Okay. We're going to look at</p> <p>12 one more document. Maybe two, but --</p> <p>13 (Exhibit 31 was marked for</p> <p>14 identification.)</p> <p>15 BY MR. SACCHET:</p> <p>16 Q. This is another document from the CDC;</p> <p>17 correct?</p> <p>18 MR. GORDON: Objection, lack of foundation.</p> <p>19 THE REPORTER: We have eight minutes left.</p> <p>20 Q. Does the title page of this document,</p> <p>21 professor, show the CDC's logo on it?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. And if you could please turn to page</p> <p>24 12 of the document, it states "FDA Device Updates:</p> <p>25 Flexible Endoscopes and Heater Coolers;" correct?</p>

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<p>1       <b>A. Yes.</b></p> <p>2       Q. Okay. If you could turn to page 15 of the</p> <p>3       document, there are a number of bullet points;</p> <p>4       correct?</p> <p>5       <b>A. Yes.</b></p> <p>6       Q. And the fourth one down says, "The</p> <p>7       orientation of the vent(s) on the devices may or may</p> <p>8       not direct the fan exhaust toward the patient or the</p> <p>9       sterile field. The exhaust from cooling fans may also</p> <p>10      play a role in the airflow within the OR, possibly</p> <p>11      facilitating movement of the aerosolized NTM into the</p> <p>12      sterile field." Do you see that?</p> <p>13      <b>A. Yes.</b></p> <p>14      Q. Is that the same mechanism of infection that</p> <p>15      Dr. Samet described in his report?</p> <p>16      MR. GORDON: Object to the form of the</p> <p>17      question, lack of foundation, assumes facts not</p> <p>18      evidence, mischaracterizes the testimony.</p> <p>19      <b>A. I -- I don't recall the detail of how --</b></p> <p>20      <b>what Dr. Samet's description was on -- on -- on the --</b></p> <p>21      <b>on the -- on devices used.</b></p> <p>22      Q. One of the issues in this litigation that</p> <p>23      was discussed in the McGovern study, which you are</p> <p>24      aware of, is that the Bair Hugger might generate</p> <p>25      convection currents that results in increased</p>	<p>1       MR. GORDON: Okay.</p> <p>2       MR. SACCHET: Yes.</p> <p>3       Q. That's correct.</p> <p>4       <b>A. Okay.</b></p> <p>5       Q. And this bullet, which is from the CDC that</p> <p>6       we established, says that "The exhaust from cooling</p> <p>7       fans may also play a role in the airflow within the</p> <p>8       OR, possibly facilitating the movement of the</p> <p>9       aerosolized NTM into the sterile field," correct?</p> <p>10      <b>A. It possibly is.</b></p> <p>11      MR. GORDON: Objection, asked and answered.</p> <p>12      Q. Possibly?</p> <p>13      MR. GORDON: You read it right.</p> <p>14      <b>A. Yes.</b></p> <p>15      Q. Okay.</p> <p>16      MR. GORDON: Are you asking him if he -- if</p> <p>17      he has any basis for --</p> <p>18      MR. SACCHET: No, I'm not, Corey.</p> <p>19      MR. GORDON: -- saying anything --</p> <p>20      commenting on that?</p> <p>21      MR. SACCHET: Please don't use the rest of</p> <p>22      my time. I'm not going to engage --</p> <p>23      MR. GORDON: Well I want -- I want to get an</p> <p>24      objection. I thought you were just, once again,</p> <p>25      reading the same sentence. If you're asking him to</p>
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<p>1       particles over the surgical site; correct?</p> <p>2       <b>A. Yes. Yes.</b></p> <p>3       Q. This bullet says that "The exhaust from</p> <p>4       cooling fans may also play a role in the airflow</p> <p>5       within the OR, possibly facilitating movement of the</p> <p>6       aerosolized NTM into the sterile field." Do you see</p> <p>7       that?</p> <p>8       MR. GORDON: Objection, asked and answered.</p> <p>9       Q. You've seen it.</p> <p>10      Does that describe a similar mechanism of</p> <p>11      moving particles or bacteria to the sterile field?</p> <p>12      MR. GORDON: Well wait, wait, wait. You</p> <p>13      started out with talking about convection currents,</p> <p>14      now you're changing gears. What -- what are you</p> <p>15      asking him?</p> <p>16      Q. I'm asking: One of the mechanisms of</p> <p>17      infection described in the McGovern study is the</p> <p>18      movement of particles from air currents generated by</p> <p>19      the Bair Hugger; correct?</p> <p>20      MR. GORDON: Well before you said convection</p> <p>21      currents, not --</p> <p>22      MR. SACCHET: Okay.</p> <p>23      MR. GORDON: You say you're changing that</p> <p>24      now?</p> <p>25      MR. SACCHET: I am.</p>	<p>1       comment on it, I object on the grounds of lack of</p> <p>2       foundation.</p> <p>3       Q. Does this describe a similar mechanism of</p> <p>4       infection as noted by McGovern et al in the study that</p> <p>5       you have reviewed?</p> <p>6       MR. GORDON: Object to the form of the</p> <p>7       question, also lack of foundation, also</p> <p>8       mischaracterizes the evidence.</p> <p>9       <b>A. I'm not sure it --</b></p> <p>10      <b>It's un -- it's unclear. I mean just that</b></p> <p>11      <b>sentence, I can't figure out -- I -- I -- I'm not --</b></p> <p>12      <b>unclear as to whether -- how this relates to what</b></p> <p>13      <b>McGovern is saying.</b></p> <p>14      Q. Did you try to shore up your</p> <p>15      misunderstanding or questions about that statement?</p> <p>16      <b>A. Well I mean you just -- you just showed me</b></p> <p>17      <b>this, --</b></p> <p>18      Q. Okay. So you -- you didn't investigate --</p> <p>19      <b>A. -- so how could I --</b></p> <p>20      Q. You didn't investigate this.</p> <p>21      <b>A. Not when --</b></p> <p>22      <b>No. I mean you asked me this question</b></p> <p>23      <b>about --</b></p> <p>24      Q. You didn't know about it.</p> <p>25      <b>A. -- a minute before. I didn't know about</b></p>